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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/418,536	10/14/1999	DANIEL J. POWERS	10981567-1	9017

24737 7590 06/22/2004

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER

OROEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/418,536	Applicant(s) POWERS ET AL.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/19/04 (Appeal).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Appeal

1. The Applicant's appeal filed 3/19/04 has been fully considered and is convincing, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102/103

2. Claims 1-12, 14 and 18-28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Skelton et al. (US 6292692).

Skelton et al. disclose a defibrillation device operated under pass control enabling the device to be reconfigured for use by individuals with different levels of training (col. 4 @ 21-24; col. 5 @ 26-46). The treatment device (10) includes a printer (60), a display (24), keys (68) for menu selection, and keys (70) for pass-code entry and feature setting (col. 10 @ 15-52). Audio recording is disclosed (col. 9 @ 54-56; col. 7 @ 66 – col. 8 @ 4). The outputs of various treatment device modules can be graphically displayed (col. 9 @ 64-67). A treatment summary is created that records pace markers, time indications and key events (col. 7 @ 26-35). Access to the recorded log can be restricted (col. 10 @ 53 – col. 11 @ 27).

Skelton et al. disclose:

- 1) deployment of a defibrillator (col. 3 @ 40-42),
- 2) monitoring of the ECG data (col. 3 @ 25-29; col. 5 @ 37-39),
- 3) recording the ECG data and display same in an incident review mode on the same screen. The pulse data (col. 4 @ 12-16) including the waveform (col. 8 @ 24-26) is provided to supplement the defibrillation therapy. The data is recorded for review (col. 6 @ 15-25); accumulated ECG data can

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be reviewed (col. 12 @ 13-22). The data displayed in figure 4 reference number 98 (a) is an ECG trace. The means to control which waveform is displayed is disclosed in figure 10, reference number 162. The ECG waveform displayed on the screen is controlled as shown in figure 10 using the buttons (70) associated with the "Trace Menu" window (162). The waveform could be the current waveform or a historical waveform (col. 6 @ 15-25; col. 12 @ 13-22), and

4) displaying recorded ECG data off-line by way of the printer strip (col. 10 @ 64-67).

As to displaying the recorded ECG data on the defibrillation screen of the defibrillator while the patient is being monitored, Skelton et al. teach patient monitoring and data display as two separate activities; the data display does not limit the patient monitoring. Skelton et al. monitor the pulse data/ ECG/ pulse waveform of the patient (col. 4 @ 12-16 and 63-65; col. 5 @ 37-39; col. 8 @ 24-26). The monitoring is ongoing/ continuous (col. 3 @ 24-29; col. 4 @ 63-65) enabling the user to review any of the historical data accumulated by the device (col. 12 @ 14-16) and/ or enabling the ECG analysis module to send a permissive signal to the SAED defibrillator medical treatment module so the user can discharge the defibrillation capacitors treating the patient (col. 5 @ 49-55).

As to displaying previously recorded and currently monitored information simultaneously on the screen, ECG data is monitored (col. 5 @ 37-39; col. 8 @ 24-26) and currently monitored ECG data is displayed on the screen (col. 5 @ 37-39; col. 64-67). The monitoring is ongoing/ continuous (col. 3 @ 24-29; col. 4 @ 63-65). Recorded data is made available for review (col. 6 @ 15-25)/ accumulated ECG data can be reviewed (col. 12 @ 13-16), hence enabling the user to review any of the historical data accumulated by the device. Based on operator selection, up to three waveforms can be displayed on the screen (figure 4 (98 a-c); col. 12 @ 10-29), hence the two waveforms

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displayed simultaneously on the screen are read as the previously recorded ECG data and the currently monitored EGC data.

As to recorded ECG data being displayed on the display for the user, the medical treatment device (10) includes treatment modules (12-16) (col. 3 @ 29-33). The device (10) enables medical treatment modules, one module being ECG monitoring (col. 5 @ 37-39). The data monitoring operation includes recording the data, the data used at the time of treatment or recorded for later use (col. 2 @ 3-10; col. 13 @ 57-63). The recorded data is made available to the user on the display (24) (figure 3). The recorded output of the ECG module is graphically displayed (figure 4 - 98 a) (col. 9 @ 64-67). Accumulated data, including recorded ECG data, is displayed (col. 12 @ 10-16).

As to the recorded ECG data being displayed simultaneously with currently monitored information, the display allows graphic display of three data traces (figure 4). The traces shown on the screen can be altered (figure 8; col. 12 @ 13-22; col. 11 @ 28-30 ; col. 13 @ 44-48). As to the claimed invention, Skelton et al. is read as teaching the display of two traces (col. 12 @ 16-22), one is the currently monitored ECG (col. 13 @ 57-61) and the second is recorded ECG data (col. 12 @ 13-22).

In the alternative, Skelton et al. teach levels of treatment are made available to caregivers based on their skill level (col. 2 @ 5-10; col. 4 @ 21-24; col. 5 @ 26-45), the levels of treatment controlled by passcode (col. 5 @ 39-45) that enable authorized caregivers to display the information needed to provide patient care (col. 9 @ 64 – col. 10 @ 6; col. 10 @ 11 – col. 11 @ 31;

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col. 12 @ 10-28; col. 13 @ 44-48 and 57-61; col. 6 @ 18-27). Skelton et al. teach simultaneously displaying previously recorded and currently monitored information on the screen. ECG data is monitored (col. 5 @ 37-39; col. 8 @ 24-26), the monitoring being ongoing/continuous (col. 3 @ 24-29; col. 4 @ 63-65). Currently monitored ECG data is displayed on the screen (col. 5 @ 37-39; col. 64-67). Recorded data is made available for review (col. 6 @ 15-25)/ accumulated ECG data can be reviewed (col. 12 @ 13-16), hence enabling the caregiver to review historical data accumulated by the device. Based on caregiver selection, up to three waveforms can be displayed on the screen (figure 4 (98 a-c); col. 12 @ 10-29), hence given the caregiver has appropriate passcode access, it is an obvious teaching to display two waveforms simultaneously on the screen, the previously recorded ECG data and the currently monitored EGC data.

Claim Rejections - 35 USC § 103

3. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6292692) in view of Rockwell et al. (US 6141584), or in the alternative, as obvious over Skelton et al. (US 6292692) in view of Rockwell et al. (US 6141584).

As discussed in paragraph 2 of this action, Skelton et al. disclose the claimed invention except for the replay step occurring automatically without user activation (claim 4) and when the patient is disconnected from the device (claim 12).

Rockwell et al. disclose a defibrillator and communication system and teach that an event summary can be generated automatically at handoff (col. 9 @ 36-38; col. 12 @ 12-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the replay step occurring automatically without user activation and when the patient is disconnected

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from device/ ECG is displayable offline in the Skelton et al. device in order to enable the care givers to review the data critical times, such as movement to a new machine or situation, to ensure patient care is progressing in an optimum fashion, and to ensure key treatments and historical events are properly noted by the medical personnel so that proper care and follow-up treatment occurs (col. 12 @ 20-24).

4. Claims 13 and 15-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Skelton et al. (US 6292692) in view of Powers et al. (US 5879374), or in the alternative, as obvious over Skelton et al. (US 6292692) in view of Powers et al. (US 5879374).

As discussed in paragraph 2 of this action, Skelton et al. disclose the claimed invention except:

- activation of the incident review mode in response to insertion of the battery, and
- offering the replay option when the defibrillator is turned off or when the battery is inserted.

Powers et al. disclose an external defibrillator with automatic self-testing prior to use.

Powers et al. teach that it is known to use the insertion of a battery as the trigger to automatically

generate a test signal. The test signal initiates a plurality of preset self-tests or activities within the defibrillator (col. 2 @ 57 – col. 3 @ 10). It is an obvious design choice that the insertion of the battery could activate the incident review mode and/or initiate an offer to replay the recorded data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the battery insertion to trigger the activation of the incident review mode and/ or the replaying

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of the stored data in the Skelton et al. device in order to gain quicker access to the incident review mode and/or the stored data.

Powers et al. teach that it is known use a gate array as a system monitor in the scenario of low power. Low power is viewed as equivalent to an impending system shutdown, hence it is an obvious design choice to have the ASIC (application specific integrated circuit) perform various tasks at the low power or shutdown point including offering to replay the stored data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the offer to replay the stored data at shutdown in the Skelton et al. device in order to keep the rescue personnel advised of the events to date in the rescue operation.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular and After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

fpo
6-1604

Angela D. Sykes

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